LABEL IN PART: (Can) "500 Doses Anchor Anti-Blote A Bloat Preventive for Cattle Veterinary Use Only * * * Each 2 Pounds Contain: Active Ingredients: Procaine Penicillin G, 37,500,000 Units."

LIBELED: 7-6-56, S. Dist. Iowa.

CHARGE: 502 (l)—when shipped, the article contained penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law; and the article had not been exempted from requirements of certification by regulations.

DISPOSITION: 9-7-56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5163. Dainty-Maid Service drug and device and Dainty-Maid Personal Powder (2 seizure actions). (F. D. C. No. 33575. S. Nos. 54-165 L, 54-167 L.)

QUANTITY: 84 pkgs. of *Dainty-Maid Service* and 35 ctns. of *Dainty-Maid Personal Powder* at Detroit, Mich.

SHIPPED: 6-4-52 and 7-7-52, from Middlefield, Conn., by Dainty Maid, Inc.

LABEL IN PART: (Pkg.) "Dainty-maid Service"; (ctn.) "Dainty-maid Personal Powder * * * Contains: Boric Acid, Zinc Sulfate, Salicylic Acid, Sodium Chloride and Tannic Acid."

ACCOMPANYING LABELING: Booklets entitled "Why must this crucial subject be Hush-Hush?" and "Profitable Suggestions For The New Dealer"; leaflets entitled "Here is an opportunity you can't afford to miss," "A Dignified Fascinating New Profession," and "Modern Heat Therapy"; charts entitled "Eight Reasons for Owning a Dainty-Maid Service"; and book entitled "Mary Coleman's Training Course In Personal Hygiene."

RESULTS OF INVESTIGATION: Each *Dainty-Maid Service* package contained 1 rubber douche bag, 1 porcelain vaginal syringe, 1 carton of *Dainty-Maid Personal Powder*, 2 pieces of rubber tubing, 1 rubber rectal tube, 1 glass "Earigator," 1 metal clamp, 1 plastic measuring scoop, and 1 leaflet entitled "Instructions."

LIBELED: 9-9-52, E. Dist. Mich.; amended 1-27-56.

CHARGE: 502 (a)—when shipped, the labeling of the articles contained false and misleading representations that the articles provided an adequate and effective treatment for preventing women from fading early in life and becoming nagging, irritable, cruel, emaciated, and scrawny; for preventing rough and pimpled skins, wrinkles on young faces, headaches, tiredness, enervation, and constant fatigue; for providing a buoyant, vibrant life; for increased vaginal discharge, leucorrhea, *Trichomonas vaginalis*, nonspecific vaginitis, and pelvic inflammatory conditions; for providing increased circulation of the blood throughout the entire body; for diseased organs, painful menstruation, and inflammation of the bladder; for stimulating the circulation, so that the glands function naturally; for minimizing "hot flashes" in older women, combatting all kinds and conditions of feminine disorders, and clearing up and preventing the occurrence of many of the most distressing of women's diseases and deplorable aftereffects; for menopausal symptoms, such as "hot flashes," nervous irritability, peevishness, and depressions; for senile vaginitis, painful menstruation, and profuse menstruation; for preventing and destroying ovarian cysts; and for falling of the womb, anteversion

of the womb, retroversion of the womb, and chronic bladder ailments; and that the articles were safe for frequent and even daily use as a douche; and 502 (f) (1)—the articles, when shipped and while held for sale, failed to bear adequate directions for use in the conditions for which they were intended, namely, the conditions hereinbefore described.

DISPOSITION: Dainty Maid, Inc., appeared as claimant and filed an answer to the libel, denying that the products were misbranded as alleged and asserting that only one proceeding was permissible under Section 304 (a), as the alleged misbranding in each of the proceedings had not been the basis of a prior judgment in favor of the United States; and, further, the Secretary had not found any of the circumstances that would permit multiple seizures.

The Government moved to strike the portions of the claimant's answer dealing with the multiple seizures' provision of the Act. The claimant then moved for dismissal of the libel or removal of the proceedings to the Southern District of New York, which was denied on March 9, 1954.

The claimant appealed from the above order to the United States Court of Appeals for the Sixth Circuit. The Government moved to dismiss the appeal, which motion was granted in the following opinion on November 19, 1954 (216 F. (2d) 668):

STEWART, *Circuit Judge:* "Proceeding under the Federal Food, Drug and Cosmetic Act, the United States filed two libels of information in the district court, seeking condemnation of a number of allegedly misbranded articles of device and drug and accompanying printed material. The statute forbids multiple seizures, permitting not more than one libel for condemnation based upon the same alleged misbranding, except '(1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction or libel for condemnation proceeding under this chapter, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.' 21 U. S. C. A., § 334 (a).

"Appellant filed as claimant in each case and interposed answers, affirmatively asserting that the alleged misbranding in each of these proceedings had not been the basis of a prior judgment in favor of the United States, that the Secretary had not found any of the circumstances that would permit multiple seizures, and that consequently only one proceeding was permissible under the provisions of 21 U. S. C. A., § 334 (a).

"Appellee moved to strike these defenses, claiming that the alleged misbranding had been the basis of a prior judgment in favor of the United States entered in 1948 in the Middle District of Pennsylvania, entitled, United States of America v. 13 Sets More or Less of an Article of Drug and Device Labeled in part 'Dainty-Maid Service,' which appellant had permitted to go to judgment by default.

"It appears that the labeling which was the subject of this prior adjudication was similar to, but not identical with the alleged misbranding in the present proceedings.

"Appellant filed a cross-motion for an order dismissing the libels, or either of them, and it is from the district court's denial thereof that this appeal was taken. Appellee has moved to dismiss the appeal on the ground that the denial of a motion to dismiss a libel of information filed pursuant to the Federal Food, Drug and Cosmetic Act is not an appealable order.

"The question which appellant would have us now decide is whether the statute permits multiple seizures of allegedly misbranded articles when the prior adjudication in favor of the United States involves similar but not the same labeling.

"Appellant contends that the phrase 'such misbranding' in the statute was intended to and does mean 'the same misbranding,' and that multiple seizures are permissible only against the identical labeling as was the subject

of the prior adjudication. The question is a novel one, but we have concluded that it is prematurely before us, and that appellee's motion to dismiss this appeal must be granted.

"It is conceded that the order appealed from is not a final decision from which an appeal would lie under the provisions of 28 U. S. C., § 1291. Appellant points out, however, that § 334 (b) of the Federal Food, Drug and Cosmetic Act provides that the procedure in condemnation cases under the Act 'shall conform, as nearly as may be, to the procedure in admiralty'; 21 U. S. C. § 334 (b), and appellant rests this appeal upon 28 U. S. C., § 1292 (3) which gives us jurisdiction of appeals from 'interlocutory decrees of such district courts or the judges thereof determining the rights and liabilities of the parties to admiralty cases in which appeals from final decrees are allowed.' It is appellant's position that the statute conforming the procedure in this type of case 'as nearly as may be, to the procedure in admiralty,' requires that this appeal be governed by principles of appellate jurisdiction in admiralty, and that in admiralty such an order as is here involved would be appealable. We think both contentions are incorrect.

"In 443 Cans of Frozen Egg Product v. United States, 226 U. S. 172 (1912), the Supreme Court had before it the claim that an almost identical clause in the predecessor Food and Drug Act of 1906 operated to make appeals in condemnation cases under that Act subject to the statutes applicable to appeals in admiralty. The Supreme Court rejected the contention, saying, 'The Act makes no reference, in conforming the proceedings as near as may be to those in admiralty, to appellate procedure. It leaves that to be determined by the nature of the case and the statutes already in force. . . .

"'We do not think it was intended to liken the proceedings to those in admiralty beyond the seizure of the property by process in rem, then giving the case the character of a law action, with trial by jury if demanded and with the review already obtaining in actions at law.' 226 U. S. 182, 183.

"Although the 443 Cans of Frozen Egg Product case was decided in a somewhat different context, we think the decision remains entirely valid under the existing statutes, and dictates rejection of appellant's argument.

"It may be added that even in admiralty it does not appear that the order here complained of would be an appealable one. The Maria, 67 F. (2d) 571 (C. A. 2, 1933); cf. Emerick v. Lambert, 187 F. (2d) 786, 788 (C. A. 6, 1951).

"The rights and liabilities of the parties in this case have not been finally determined by the order of the district court. Whether the misbranding here alleged is 'such misbranding' as was the basis of the prior judgment is primarily a factual question, and this court is not a trier of facts. The ends of justice will be better served by deferring review until after a hearing and final judgment in the district court on the merits. The parties are entitled, no less than we, to the benefit of a record containing factual findings and legal conclusions that can be intelligently reviewed on appeal.

"The motion to dismiss the appeal is granted."

The Government moved for Summary Judgment, which was denied on December 29, 1955. The Government then made a motion to amend the libels to include the above-mentioned charge of misbranding under Section 502 (f) (1), which motion was granted on January 27, 1956.

The case went on to trial, and on March 23, 1956, the jury returned a verdict for the Government.

On May 9, 1956, the court entered the following decree of condemnation:

LEVIN, *District Judge:* "These actions were commenced by the filing of two libels on September 9, 1952, in the United States District Court for the Eastern District of Michigan, Southern Division. Dainty Maid, Inc., of Middlefield, Connecticut, intervened and filed a claim of ownership and an answer. There being common questions of law and fact involved in both actions, the two actions were consolidated for trial; and upon claimant's demand for a jury trial, were tried before a jury beginning on March 20, 1956.

"Now the jury, having heard the evidence and entered a verdict in favor of the libellant, the United States of America, finding that the articles of drug and device seized herein were misbranded as alleged in the libels, it is hereby

"ORDERED, ADJUDGED, AND DECREED that the 84 packages, more or less, of an article of drug and device labeled in part 'Dainty-Maid Service' and accompanying labeling, and 35 cartons, more or less, of an article of drug labeled in part 'Dainty-Maid Personal Powder' and accompanying labeling, are hereby condemned pursuant to 21 U. S. C. 334 (a).

"The claimant, Dainty Maid, Inc., by its attorney, Arthur D. Herrick, having petitioned the court to deliver the condemned articles to the claimant for the purpose of relabeling under the provisions of 21 U. S. C. 334 (d), the court hereby denies said petition and orders that the condemned articles be destroyed by the United States Marshal for this district, provided that the Marshal is directed to deliver to a qualified representative of the Secretary of the Department of Health, Education, and Welfare, a quantity of the drugs, devices, and literature seized, for exhibit purposes.

"The court bases its order refusing to allow relabeling upon the following grounds:

"1. 21 U. S. C. 334 (d) provides that after entry of a decree of condemnation 'the court may by order direct that (the condemned) article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act. . . .' The court is of the opinion that this language reposes discretion in the court as to whether relabeling should be allowed.

"2. The identical drug and device involved in the present action was the subject of a prior condemnation proceeding in the United States District Court for the Middle District of Pennsylvania, which was determined on August 23, 1948, and in which it was found that the Dainty-Maid Service there involved was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act because the article was falsely represented in its labeling as being effective in preventing leucorrhea and other conditions associated with a vaginal discharge.

"3. The labeling involved in the present case, which arose four years later, made similar representations that the Dainty-Maid Service would effectively prevent and treat leucorrhea, ovarian cysts, and a host of other conditions which give rise to a vaginal discharge. Such claims were made in all of the labeling associated with the condemned article including the booklet 'Why Must This Crucial Subject Be Hush-Hush?' The latter booklet, in particular, was a calculated and designed attempt to effectively make such unwarranted claims while appearing to disclaim such intention.

"4. Testimony at the trial by outstanding experts in the fields of gynecology, dermatology, internal medicine and pathology convincingly demonstrated that the Dainty-Maid Syringe and Powder would not be effective in treating or preventing the serious disease conditions for which it was recommended in its labeling. In fact, they testified that because of the pressure built up by the device when used as recommended, it presented a serious health hazard. They testified that when used as directed it could force fluid containing disease organisms into the cervical canal and fallopian tubes which could result in serious impairment to health. Furthermore, by persuading women suffering from conditions manifested by a vaginal discharge to forego proper medication, reliance upon this device and powder could cause the aggravation of diseases which must be treated promptly if a cure is to result.

"5. Both because of the danger to health involved through the use of this syringe and powder, and because of the flagrant misbranding which was continued despite a prior court decree finding that the claims were false and misleading, the motion for release of the seized articles for the purpose of relabeling is denied.

"WHEREFORE, the United States Marshal for this District is directed pursuant to 21 U. S. C. 334 (d) to dispose of the articles seized by appropriate destruction of the seized articles, except for ten of the Dainty-Maid Service kits which he is directed to turn over to a representative of the United States Food and Drug Administration for exhibit purposes."

On August 8, 1956, the court entered an order amending the decree of condemnation to provide for the delivery to the Food and Drug Administration of all the drugs, devices, and literature seized.